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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,356	09/11/2003	Duran Yetkinler	SKEL-012	6769

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/661,356

Applicant(s)

YETKINLER ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,6-11,18-23 and 31-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-11,18-23 and 31-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The limitation, "4 to 10 cubic centimeters" is new matter.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 7-9, 11, 31-33, 36-38, 40-41 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Constantz et al. (US 6,149,655).

Constantz et al. disclose a method of introducing calcium phosphate cement for orthopedic applications utilizing a cement delivery means such as a needle wherein the needle is vibrated to enhance perfusion of cement (col. 25, lines 38-59, col. 27, lines 11-57, col. 28, lines 49-67 and col. 29, lines 1-67).

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Constantz et al. clearly disclose that vibration is utilized to enhance cement infiltration. Thus, when vibration is stopped, infiltration would also be "substantially stopped."

Regarding claim 31, Constantz et al. disclose removal of marrow matter prior to introduction of calcium phosphate (col. 26, lines 43-48).

### ***Claim Rejections - 35 USC § 102/103***

Claims 10 is rejected under 35 U.S.C. 102(b) as anticipated by Constantz et al. (US 6,149,655) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Constantz et al. (US 6,149,655).

Although Constantz et al. do not make an explicit reference to a vibratory element attached to the cement delivery means or needle such an element would be inherently necessary in order to vibrate the cement delivery needle.

One of ordinary skill in the art would have found it obvious to provide a vibratory element attached to the needle in order to vibrate the needle. To support this position, the Examiner directs Applicants' attention to Sproul (US 6,832,988) who discloses an ultrasonic pulse generator or "vibratory element" 92 attached to an ultrasonic probe 91 in order to vibrate the probe (Fig. 7 and col. 7, lines 15-47).

The method steps of claim 10 are rendered obvious by the above discussion.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655) in view of Sproul (US 6,832,988).

Constantz et al. disclose all elements of the claimed invention except for the step of aspirating marrow from cancellous bone.

Sproul teaches maceration and liquefaction of diseased tissue followed by aspiration during vertebroplasty (col. 1, lines 29-38 and col. 7, lines 15-47).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized aspiration, as taught by Sproul, for removing diseased tissue during vertebroplasty according to the method of the combination of Constantz et al. and Sproul.

Claims 18-21, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito (US 6,340,299) in view of Smith et al. (US 4,653,957).

Saito discloses a system for delivering a cement including a delivery device or cannula 35 and a vibration generating mechanism or "vibratory element" 11 for vibrating the cement delivery device (Fig. 2, col. 5, lines 11-67, col. 6, lines 37-45 and col. 7, lines 18-39).

Saito discloses all elements of the claimed invention except for a pneumatic vibration generating mechanism or "vibratory element" 11.

Pneumatic vibration generating means are well known as evidenced by Smith et al. (col. 3, lines 55-68).

It would have been obvious to one of ordinary skill in the art to substitute a pneumatic vibration generating mechanism as, for example, taught by the Smith et al. reference for the vibration generating mechanism of the Saito device wherein so doing would amount to mere substitution of one functionally equivalent vibration generating mechanism for another within the same art and the selection of any of these mechanisms would work equally well in the claimed device.

Claims 18-23, 26, 34, 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655) in view of Seki (US 4,961,817).

Constantz et al. discloses all elements of the claimed invention except for a pneumatic vibratory element.

Seki et al. teach a pneumatic vibrator 3B for vibrating a needle-like member 3A (Figure 7 and col. 5, lines 37-47).

It would have been obvious to one of ordinary skill in the art to utilize a pneumatic vibrator or "vibratory element," as taught by Seki, for the purpose of vibrating the needle of Constantz et al., since it was known in the art to utilize a pneumatic vibrator to vibrate a needle-like member.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655).

Constantz et al. disclose that the amount of flowable calcium phosphate cement utilized depends on the nature of the vertebral body being treated (col. 27, lines 2-9).

Constantz et al. disclose all elements of the claimed invention except for the amount of cement being about 4 to 10 cubic centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized 4 to 10 cubic centimeters of cement, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### ***Response to Arguments***

Applicant's arguments filed on June 24, 2005 have been fully considered but are not persuasive with respect to claims 1-2 and 6-11 for the following reasons.

With regard to Applicants' argument that Constantz et al. do not disclose the limitation "when vibration is stopped, perfusion of cement also substantially stops," it is the Examiner's position that the use of vibration enhances infiltration of cement. Thus, when vibration is stopped, infiltration is also "substantially stopped."

Applicants' arguments with respect to claims 18-23 and 26 are moot in view of the new grounds of rejection.

The Terminal Disclaimer filed on June 24, 2005 overcomes the double patenting rejections made in the previous office action.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Amuadho Ramana*  
September 5, 2005

  
**EDUARDO C. ROBERT**  
**PRIMARY EXAMINER**